TITLE SLIDE: Implementation Science in 2013

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SLIDE 1: Overview

- Implementation Science Perspectives on eHealth
  - Evidence Integration Triangle
  - RE-AIM and Equity Issues
- Pragmatic Approaches and eHealth Review
- Reflections, Needs and Pragmatic Example
  - My Own Health Report study
- Funding, Conclusions, Q&A

SLIDE 2: NCI Implementation Science

Team Vision
To achieve the rapid integration of scientific evidence, practice, and policy, with the ultimate goal of improving the impact of research on cancer outcomes and promoting health across individual, organizational and community levels.
IS Team Website: http://cancercontrol.cancer.gov/IS/

SLIDE 3: RE-AIM Realist or Precision Medicine Question*

- What percent and types of patients are ***Reached***;
- For whom among them is the intervention ***Effective***; in improving what outcomes; with what unanticipated consequences;
- In what percent and types of settings and staff is this approach ***Adopted***;
- How consistently are different parts of it ***Implemented*** at what cost to different parties;
- And how well are the intervention components and their effects ***Maintained***?

*Pawson R, et al. *J Health Serv Res Policy* 2005;10(S1):S21-S39.
Gaglio B, Glasgow RE. Evaluation approaches…In: Brownson R, Colditz G, Proctor E, (Eds). *Dissemination and implementation research in health: Translating science to practice*. New York: Oxford University Press; 2012. Pages 327-356.

SLIDE 4: RE-AIM—Inequity Implications

[Table]

RE-AIM Issue	Disparity	Overall Impact
Reach	30%	70% of benefit
Effectiveness	0 (equal)	70% of benefit
Adoption	30%	49% of benefit
Implementation	30%	34% of benefit
Maintenance	30%	24% of benefit

[End Table]
IS Team Presentation on Health Inequities: http://cancercontrol.gov/IS/presentations.html

SLIDE 5: Evidence Integration Triangle (EIT)

[Image] Intervention (Program/Policy) (e.g. design; key components; principles guidebook; internal and external validity) has a bi-directional connection to "Practical Progress Measures (e.g. actionable & longitudinal measures)". "Practical Progress Measures" has bi-directional connection to "Participatory Implementation Process" (e.g. stakeholder engagement; team-based science; CBPR; patient centered care). "Implementation Process" has a bi-directional connection to "Intervention (Program/Policy)". Each bi-directional arrow displays the word "Feedback" above it. This completes the circular connection from "Intervention (Program/Policy)" to "Practical Progress Measures" to "Implementation Process" back to "Intervention (Program/Policy)". Two ovals with the words, "Evidence and Stakeholders" are in the middle of the triangle. A circle encompasses the whole triangle and lists the six Multi-level contexts: (1) Intrapersonal/biological; (2) Interpersonal/Family; (3) Organizational; (4) Policy; (5) Community/Economic; (6) Social/Environment/History.[End Image]
Glasgow RE, Green LW, Taylor MV, et al. Am J Prev Med 2012;42:646-54

SLIDE 6: Evidence Integration Triangle (EIT) - A Patient-Centered Care Example

[Image] Intervention Program/Policy (Evidence-based decision aids to provide feedback to both patients and health care teams for action planning and health behavior counseling) has a bi-directional connection to "Practical Progress Measures (Brief, standard patient reported data items on health behaviors & psychosocial issues -- actionable and administered longitudinally to assess progress)". "Practical Progress Measures" has bi-directional connection to "Participatory Implementation Process" (Iterative, wiki activities to engage stakeholder community, measurement experts and diverse perspectives). "Implementation Process" has a bi-directional connection to "Intervention (Program/Policy)". Each bi-directional arrow displays the word "Feedback" above it. This completes the circular connection from "Intervention (Program/Policy)" to "Practical Progress Measures" to "Implementation Process" back to "Intervention (Program/Policy)". Two ovals appear in the center of the triangle: (1) Evidence: US Preventive Services Task Force recs. for health behavior change counseling; evidence on goal setting & shared decision making; and (2) Stakeholders: Primary care (PC) staff, patients and consumer groups; PC associations; groups involved in meaningful use of EHRs, EHR vendors. A circle encompasses the whole triangle and lists the multi-level context for this example: Dramatic increase in use of HER; Primary Care Medical Home; CMS funding for annual wellness exams; Meaningful use of EHR requirements.[End Image]

Glasgow RE, Green LW, Taylor MV, Stange KC. AJPM (in press, 2012)

SLIDE 7: The Pragmatic-Explanatory Continuum Indicator Summary (PRECIS)

Describes ten domains that affect the degree to which a trial is pragmatic or explanatory.

1. Participant eligibility criteria
2. Experimental intervention flexibility
3. Practitioner expertise (experimental)
4. Comparison intervention
5. Practitioner expertise (comparison) outcome

6. Follow-up intensity
7. Primary trial outcome
8. Participant compliance
9. Practitioner adherence
10. Analysis of primary

Thorpe KE, et al. *J Clin Epidemiol* 2009; 62: 464–475, *Can Med Assoc J* 2009; 180(10)

SLIDE 8: PRECIS

[Image]Two figures that each show a circle with 10 lines emanating from the center. The lines are titled the following:

1. Follow-up Intensity
2. Practitioner Expertise (Comparison)
3. Flexibility of Comparison Intervention
4. Practitioner Expertise (Experimental)
5. Flexibility of Experimental Intervention
6. Eligibility Criteria
7. Primary Analysis
8. Practitioner Adherence
9. Participant Compliance
10. Outcomes

In Figure 1, the lines are connected at points near the ends indicating a more pragmatic trial. In Figure 2, the lines are connected at points close to the center indicating a more explanatory trial.
[End Image]

SLIDE 9: e HEALTH REVIEW

[Figure] Displays the process for identifying and excluding articles to be included in the e health review. Initial review started with 1926 papers identified. Of those, 1459 were excluded and 467 included in the initial review. For the further subsection of the 467 used in the PRECIS e health review, 139 publications (across 113 studies) were determined to be cancer-related. Of those, 97 were determined to be T1 and 16 were determined to be T2. [End Figure]

SLIDE 10: eHEALTH REVIEW RESULTS

- Little variability in PRECIS scores across all studies
- Most fell midway along the PRECIS continuum
  composite mean = 3.12 (domain range, 2.7-3.6)
- Few reported practical feasibility criteria
  composite mean = 1.98 (domain range, 1.5 to 2.8)
- Practical feasibility scores rated lower than PRECIS
- Significant differences by intervention settings, target population, year published, and translation phase
- Trend analysis
  - Significant increase—Experimental intervention flexibility domain
  - Significant decrease—Intervention resources domain

Sanchez et al. A Systematic Review of eHealth Cancer Prevention and Control Interventions: New Technology, Same Methods and Designs? Transl Behav Med. Under Review.

SLIDE 11: Pragmatic Explanatory Continuum Indicator Summary (PRECIS) and Practical Feasibility "Spoke and Wheel" Diagrams:

(a) PRECIS lowest versus highest scored studies*; (b) Practical feasibility lowest versus highest scored studies

[Image 1] PRECIS figure (a) that shows a circle with 10 lines emanating from the center. The lines are titled the following:

1. Follow-up Intensity
2. Practitioner Expertise (Comparison)
3. Flexibility of Comparison Intervention
4. Practitioner Expertise (Experimental)
5. Flexibility of Experimental Intervention
6. Eligibility Criteria
7. Primary Analysis
8. Practitioner Adherence
9. Participant Compliance
10. Outcomes

In Figure a, the lines are connected at connected once by an example study that is more pragmatic so it connects further out on the spokes and the second example the lines are connected at points close to the center indicating a more explanatory trial.
[End Image]

[Image 2] This figure is also like a spider web, but only has 8 spokes. The spokes are:

1. Program Sustainability
2. Adaptation/Change
3. Participant Engagement
4. Participant Representativeness
5. Setting Representativeness
6. Intervention Resources
7. Monetary Costs
8. Unintended Consequences

Again two examples of publication results are shown, one that is very close to the center of the web indicating low practical feasibility and another that is further out on the spokes indicating higher practical feasibility. [End Image]

* Maximum and minimum PRECIS scores based on only studies for which all domains were scored.

Sanchez et al. A Systematic Review of e Health Cancer Prevention and Control Interventions: New Technology, Same Methods and Designs? Transl Behav Med. Under Review.

SLIDE 12: Pragmatic Measures

1. **Required Criteria**

- Important to stakeholders
- Burden is low to moderate
- Broadly applicable, has norms to interpret
- Sensitive to change

2. **Additional Criteria**
   - Actionable
   - Low probability of harm
   - Addresses public health goal(s)
   - Related to theory or model
   - "Maps" to "gold standard" metric or measure

Riley, W. T. & Glasgow, R. E. Pragmatic measures… *Am J Prev Med. 2013.*

SLIDE 13: Dissemination and Implementation Measures Initiative

GEM-D&I Homepage: www.gem-beta.org/GEM-DI

- D&I workspace launched on GEM in March 2012
- 120 measures available, across 45 constructs.

Purpose:

- To engage research community and stakeholders in sharing, commenting on, and rating measures of key D&I constructs.
- To provide a resource for investigators in writing grants and designing studies, and eventually, data sharing among interested parties to advance science

SLIDE 14: EHR Measures for Primary Care

[Table]

Domain	Final Measure (Source)
1. Demographics	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status. Multiple sources including: Census Bureau, IOM, and *National Health Interview Survey (NHIS)*
2. Overall Health Status	1 item: BRFSS Questionnaire
3. Eating Patterns	3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. *Am J Prev Med* 2011;40(1):67-71]
4. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. *Br J Sports Med* 2011;45(6):473-474]
5. Stress	1 item: Distress Thermometer [Roth AJ, et al. *Cancer* 1998;15(82):1904-1908]
6. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. *Psychosomatics* 2009;50(6):613-621]
7. Sleep	2 items:

	a. Adapted from BRFSS b. Neuro-QOL (Item PQSLP04)
8. Smoking/Tobacco Use	2 items: Tobacco Use Screener (Adapted from YRBSS Questionnaire)
9. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. *J Gen Int Med* 2009;24(7):783-788]
10. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. *Arch Int Med* 2010;170(13):1155-1160]

[End Table]

SLIDE 15: Pragmatic Study Methods:

Key Characteristics

- Questions from and important to stakeholders
- Multiple, heterogeneous settings
- Diverse populations
- Comparison conditions are real-world alternatives
- Multiple outcomes important to decision and policy makers

Thorpe KE et al., *Can Med Assoc J*, 2009;180:E47-57
Tunis SR et al. Practical clinical trials…*JAMA* 2003;290:1624-1632
Glasgow RE et al. Practical clinical trials…*Med Care* 2005;43(6):551-557

SLIDE 16: My Own Health Report (MOHR) Automated Assessment Tool

[Image] Showing an image of the checklist tool which the patient fills out this is connected by a uni-directional arrow which points to a box with the text "Database of text messages and triggers." The database is connected to two boxes (1) Summary display and printout for patient and (2) Summary display and printout for physician. These lead to a final box, "Action Plan printout." Additionally the first box showing the patient completing the form is connected to a separate box that says "Report Data stored in database" which is then connected through a uni-directional arrow to a box titled "Research Analysis."[End Image]

SLIDE 17: MOHR Project—Key Points

- Cluster randomized trial of 9 pairs of clinics. Approximately half of clinics community health centers, others AHRQ-type PBRN clinics
- Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids
- **What is delivered** - e.g., automated assessment tool, feedback, goal setting materials, follow-up are **standard**
- **How this is delivered is customized** to setting
- Study goal = Sustainable, routine use of intervention

Fact Sheet Available at:
http://cancercontrol.cancer.gov/IS/pdfs/MOHR_Executive_Summary_2-22-2013.pdf

[Image] Map of US showing Implementation trial sites: Oregon, California, Minnesota, Texas, Virginia, North Carolina [End Image]

SLIDE 18: Pragmatic Features

[Table]

Relevant	Diverse, real-world primary care settings; and staff who do all the intervention
Rigorous	Cluster randomized, delayed intervention design
Rapid	One year from concept, planning, and execution, low cost, and cost informative
Resource Informative	Low cost; studying costs and cost-effectiveness under different delivery conditions
Transparent	Report on adaptations, failures, lessons learned

[End Table]

SLIDE 19:

"The significant problems we face cannot be solved by the same level of thinking that created them." Albert Einstein

SLIDE 20: Russ' Observations and Reflections on Evidence

SLIDE 21: Types of Evidence Needed: A New "Bold Standard"? The 5 R's

- Relevant (to stakeholders)
- Rapid and Recursive—iterative; ongoing learning
- Rigorous (redefined to include robustness and replication)
- Resources Reported
- Replication

Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Submitted—available by request

SLIDE 22: Relevance

- Studies with or generalizable to:
    - Real-world settings, including low- cost sites
    - Range of staff intervention models
    - Range of end users, consumers, participants
    - Typical conditions of administration and assessment
- Can get quick idea from CONSORT PRECIS criteria

Thorpe KE, Zwarenstein M, Oxman AD et al. Journal Clin Epidemiol. 2009; 62: 464–475

[Image] Cartoon showing two people sitting at a desk looking at papers. One says 'But if it's not participatory action research, what is it?' and the other person responds 'hm..dictatorial inaction research?...alienated sedentary research? Autocratic twiddle-your-thumbs research?' [End Image]

SLIDE 23: Rapid and Recursive*

- Pace of research (17 years for 14% of data to translate) is way too slow
- Need changes in design, review, measures, publication, and culture

- Many evolving, adaptive designs; several from different fields
- Across the T1-T4 cycle
- In Quality Improvement (QI) sense of continuous improvement
- Programs and policies hardly ever work perfectly when initially implemented, or as in the efficacy study
- Evidence Integration Triangle captures some of the needed iteration

*Riley, Glasgow, Etheredge, Abernethy. Pragmatic measures… *Am J Prev Med. 2013*

SLIDE 24: Traditional Timeframe for Research in Comparison to Technology

[Image] A figure showing how standard grants are outpaced by technology.
A timeline going from 2005 to 2011. On the top, is a series of boxes showing at what point major technology innovations occurred: YouTube (2005); iPhone (2007); Android (2008); iPad (2010).
On the bottom, is a series of boxes showing the key events of a grant: Grant Submit and Award (2005); Development and Pilot Testing (2006-2007); Recruit and Randomize (2008-2009); Follow-ups (2009-2010); Analyze and Publish (2011). [End Image]

SLIDE 25: Development/Validation Steps Involving Rapid e Health Learning Networks

[Image] Using the same timeframe from image on slide above, we now zoom in on a two year period and demonstrate how research could be accelerated with certain strategies. First there is a "Rapid Literature Review" which is inclusive of the grey literature and focuses on key and recent publications. Simulataneously there is the environmental scan of the practice- or industry-base with a focus on lessons learned and snowball networking. These two tasks are to be done within the target timeframe of 1 to 3 months. The next step is an evaluability assessment (RE-AIM, cost, future direction, context, and health technology) and small rapid studies (e.g., A-B, n of 1, Fractional fractorial, program changes, Version X1 and X2). These two steps are to be done within 2 to 6 months. Lastly there is Application Tests in Diverse settings (e.g., stepped wedge, pragmatic studies, replication, CER, relevant RCTs) and finally Dissemination/Evaluation (e.g., continuous monitoring, alerts, communities of practice, continuous quality improvement). These final two steps are to be completed within a target timeframe of 6 to 12 months. [End Image]

SLIDE 26: Rigorous (Devil is in the Details)

- Replication is sina qua non of causality—and severely unappreciated
- Balance of internal and external validity
- Consider and address most likely potential confounding factors

[Image] Devil [End Image]

SLIDE 27: Resource Informative

- Need to know implementation costs (as conducted) and replication costs (under different conditions)
- Need to report staff time, training, recruitment, supervision, delivery costs

- Do NOT need complete, comprehensive societal analyses of downstream consequences, etc.

SLIDE 28: What Else Do We Need?

- Harmonized measures: Common measures would help cross-study comparisons, reviews, etc.
- Convergence of results across diverse methods: e.g., RCTs, observational data, simulation modeling, natural experiments, practice-based evidence, quantitative and qualitative, etc.

SLIDE 29: All Models (and Methods) are Wrong ….Some are useful, H.L. Mencken

SLIDE 30: Types of Evidence Needed: A New "Bold Standard"? The 5 R's

- Relevant (to stakeholders)
- Rapid and Recursive—iterative; ongoing learning
- Rigorous (redefined to include robustness and replication)
- Resources Reported
- Replication

Peek, Kessler, Glasgow, Klesges, Purcell, Stange. Submitted—available by request

SLIDE 31: The Trans-NIH D&I Funding Announcement (International Investigators Eligible)

- R01 - PAR 13-055 ($500k per annum up to five years)
  R03 - PAR 13-056 ($50K per annum up to two years)
  R21 - PAR 13-054 ($275K up to two years)
- Participating Institutes: NIMH, NCI, NIDA, NIAAA, NIAID, NHLBI, NINR, NIDDK, NINDS, NIDCD, NIDCR, NCCAM, NHGRI*, NIA* & Office of Behavioral & Social Sciences Research
- Standing review committee, Dissemination and Implementation Health Research
- Three submission dates per year: February, June, October
- New Institute Added to PAR in 2013

NIH D&I Funding Announcements: http://cancercontrol.cancer.gov/funding_apply.html#is

SLIDE 31: Implementation Science Funding Opportunities

- *PCORI—and "true" patient/family-centered research*
- *"Team Science" and collaborative approaches to care transformation*
- Guidelines implementation, especially across networks
- *Patient Health Records—patient portal to EHR*
- *Collection and meaningful use of patient report measures for care and research*
- Efficiency, CEA and CER on care planning, etc.

SLIDE 32: Research Tested Intervention Programs (RTIPs)

[Image] Series of logos for several programs on Research-Tested Intervention Programs website. [End Image] http://rtips.cancer.gov/rtips/index.do

SLIDE 33: Research Tested Intervention Programs (RTIPs)

Criteria for Inclusion on RTIPs

- Intervention outcome finding(s) must be published in a peer-reviewed journal.
- The study must have produced one or more positive behavioral and/or psychosocial outcomes ($p \leq .05$) among individuals, communities, or populations.
- Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design. The intervention must have messages, materials, and/or other components that include English and can be disseminated in a U.S. community or clinical setting.
- The intervention has been conducted within the past 10 years.

How You Can Get Involved:

- Submit your intervention for RTIPs consideration: http://rtips.cancer.gov/rtips/register/index.do
- Contact the RTIPs team for questions, comments, additional information: http://rtips.cancer.gov/rtips/contact.do

Coming to RTIPs in 2013-2014: More user interactive web-based interventions

SLIDE 34: Evidence-Based Program and RE-AIM Resources

[Image] Series of screen shots for three tools: Cancer Control P.L.A.N.E.T., RE-AIM Self-Rating quiz, and RTIPs program summary. [End Image]

SLIDE 35: Key Take Home Points

Evidence means different things to different people –is almost a cultural difference

We need:

- Balance and respect for different types of evidence
- To think and evaluate broadly
- To consider evidence from multiple perspectives, and especially of potential target audience

SLIDE 36: Time for Questions

Contact me: glasgowre@mail.nih.gov
IS Team Website: http://dccps.cancer.gov/is/
IS Team Email: NCIdccpsISteam@mail.nih.gov

SLIDE 37: Additional Slides

SLIDE 38: RE-AIM Evaluability Questions or Planning for Dissemination

- What percent and what types of patients are likely to **Receive** this program;
- For whom among them is the intervention **Effective**; in improving what outcomes; what broader effects and potential negative consequences?

- What percent and what types of settings and practitioners are likely to **Adopt** this program;
- How consistently are different parts of the program likely to be **Implemented** across settings, clinicians, and patient subgroups…and at what cost;
- And how well is the eHealth program and its effects likely to be **Maintained**?

Leviton LC, et al. Evaluability assessment…*Annu Rev Public Health* 2010;31:213-233.

SLIDE 39: Future Evidence Needs and Opportunities—Keys to Advance Translation

- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Health equity impacts
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice

SLIDE 40: Future Evidence Needs and Opportunities—Keys to Advance Translation (cont.)

- Health equity impacts
- Context—key factors that may moderate results
- Scalability—potential to impact large numbers
- Sustainability
- Patient/citizen/consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice